



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2015

NOVASTEP
Mr. Gilles Audic
QA/RA Director
Espace Performance Alphasis – Batiment C1-C2
35769 Saint Gregoire
France

Re: K143146

Trade/Device Name: **Nexis® osteosynthesis snap-off screws**
Regulation Number: **21 CFR 888.3040**
Regulation Name: **Smooth or threaded metallic bone fixation fastener**
Regulatory Class: **Class II**
Product Code: **HWC**
Dated: December 9, 2014
Received: December 12, 2014

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Section
4: Indications for Use Statement

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (*if known*)
K143146

Device Name
Nexis® osteosynthesis snap-off screws

Indications for Use (*Describe*)
The Nexis® osteosynthesis compressive screws are single use devices indicated for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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Section
5: 510(k) Summary

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"510(k) Summary" as required by section 807.92(c)

Submitter	NOVASTEP Espace performance Alphasis Bâtiment C1-C2 35769 SAINT GREGOIRE France Phone : + 33 (0)2 99 33 86 50 Fax :+ 33 (0)9 70 29 18 95
Contact person	Mister Gilles AUDIC QA / RA Director Cell phone:+33 (0)6 30 93 96 08 e-mail: gilles.audic@novastep-ortho.com
Preparation date	November 27 th , 2014

Trade name	Nexis® osteosynthesis snap-off screws
Common Name	Screw, Fixation, Bone
Classification Name	Smooth or threaded metallic bone fixation fastener (21CFR 888.3040, product code HWC)
Regulatory class	II

Legally marketed predicate devices	510(k) number: K070039 Device name: Memometal Fixos screws Original applicant: MEMOMETAL TECHNOLOGIES This predicate has not been subject to a design-related recall.
Description	Nexis® osteosynthesis snap-off screws are single-use bone fixation devices intended to be permanently implanted. Nexis® osteosynthesis snap-off screws are non canulated snap-off screws made of Titanium (Alloy Ti-6Al-4V ELI).



	Nexis® osteosynthesis snap-off screws are non canulated snap-off bone screws which allow a permanent compression, thus supporting a secure osseous restoration.
Intended use	The Nexis® osteosynthesis compressive screws are single use devices intended for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.
Comparison of the technological characteristics with the predicate device	The new devices Nexis® osteosynthesis snap-off screws have similar technological characteristics in terms of material (ISO 5832-3 Implants For Surgery -- Metallic Materials -- Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy) and mechanical characteristics (ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws) and thus are believed to be substantially equivalent to the predicate Memometal Fixos screws (device reference: W-Fix) (K070039).
Performance data	<p>The biocompatibility evaluation for new devices Nexis® osteosynthesis snap-off screws was conducted in accordance with Blue Book Memorandum #G95-1 (Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing') and International Standard ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process) as recognized by FDA.</p> <p>The new devices Nexis® osteosynthesis snap-off screws have similar technological characteristics in terms of design and mechanical characteristics (Driving and removal torque, pull-out strength, torsional resistance) and thus are believed to be substantially equivalent to the predicate Memometal Fixos screws (device reference: W-Fix) (K070039).</p>
Indication for use	The Nexis® osteosynthesis compressive screws are single use devices indicated for the fixing and stabilizing the elective osteotomies of the mid foot bones and the metatarsal and phalanges of the foot only.
Clinical studies	Clinical studies were not required for this submission
Animal Studies	Animal Studies were not required for this submission
Conclusion	Nexis® osteosynthesis snap-off screws are substantially equivalent to their predicate devices Memometal Fixos screws (device reference: W-Fix) (K070039), in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.